

REMARKS

This document is filed in response to the Office Action dated May 26, 2006. This response is organized in substantially the same order as the issues appear in the Office Action. Applicants appreciate that the Examiner called their attorney regard claim elections and that she takes time to make very helpful suggestions in making amendments. The claims have been amended in most part as suggested by the Examiner. Attached to this correspondence are:

- A marked-up version of the amended claims;
- A clean version of the amended claims; and
- A Terminal Disclaimer.

Election/Restriction

Applicants affirm their election, made during a May 18, 2006 telephone interview and without traverse, to prosecute Group I, claims 1-3, 6-12, 15 and 20 which read upon SEQ ID NO:18. Claims 9, 15, and 20 are amended in consistence with this election. Claims 4-6, 13-14, and 16-19 are withdrawn from prosecution at this time without prejudice.

No change in inventorship results from this election.

Claim Objections

Claims 9 and 20 are amended to remove non-elected inventions. In addition, Claim 15 is amended to remove Claim 13 from which, among other claims, Claim 15 depends. With these amendments to correct the informalities, Applicants believe that they have overcome the objections. No new matters are introduced by these amendments.

Claim Rejections - 35 USC §112

A. Claims 2, 3, 6-12, 14 and 20 are rejected as being non-enabling under the second paragraph of §112 as being indefinite

Applicants appreciate that the Examiner made extremely helpful suggestions regarding the language of the claims. Claims 2, 3, 7-12, 14 and 20 have been amended.

Claim 6 is withdrawn from further consideration. Applicants believe that the amendments have removed the ground for the rejections.

B. Claims 1, 2, 6-8, 10, 11 and 15 are rejected under the first paragraph of §112 as being non-enabling

Claims 1, 2, 7-8, 10, 11, and 15 have been amended. Claim 6 is cancelled and withdrawn from consideration.

The Examiner states that

(A) because the word “comprising” is used in Claim 1, the claim would “read on *any human IgG Fc variant* which allows for the IgG Fc variants to comprise various mutations.” (OA page 7, second paragraph, emphases original); and

(B) because the claims recite “HuEPO-L-vFc fusion protein, **comprising..**” it would allow for the HuEPO-L-vFc fusion to comprise other sequences, mutations, and/or variants. (OA, page 7, second paragraph, emphasis original.)

As a result, the written description is non-enabling with respect to the claim language. Applicants respectfully suggest that the Examiner’s concerns are misplaced.

“Enablement is a legal determination of whether a patent enables one skilled in the art to make and use the claimed invention.” (citations omitted) *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384 (Fed. Cir. 1986). Even if some experimentation is required, so long as it is not unduly extensive, a specification can still be enabling. *Atlas Powder Co. v. E. I. Du Pont De Nemours & Co.*, 750 F.2d 1569, 1576 (Fed. Cir. 1984); *B.J. Services Co. v. Halliburton Energy Services, Inc.*, 338 F.3d 1368 (Fed.Cir.2003).

When reading the claims within the context of the specification of this instant application, one skilled in the art would recognize that the Applicants never intend that the scopes of the claims are as open-ended as understood by the Examiner. For example, see descriptions in paragraphs [0009], [0020] and [0021]. Applicants believe that they have

provided ample of written description to enable one skilled in the art to make and use the claimed invention.

Nonetheless, Applicants have amended claim 1 by replacing “comprising” with “consisting of” to allay any such concerns and to advance the prosecution of the application.

Accordingly, Applicants believe that they have addressed all grounds of the rejection through amendments and the foregoing discussions.

Double Patenting

Claims 3 is rejected on the grounds of non-statutory obviousness-type double patenting over claim 1 of US Patent US 6,900,292 B2.

A Terminal Disclaimer is filed herewith.

In addition, both claim 1, claim 3, and claim 20 are amended herein. Applicants note both claim 1, as amended, and claim 20 have additional limitation the “the recombinant HuEPO-L-vFc fusion protein exhibits *in vitro* biological activity similar to or higher than that of rHuEPO on a molar basis.” Claim 1 of US 6,900,292 B2 does not have this limitation while claim 6 and claim 12 of this ‘292 patent require that there be a limitation of the invention to “*in vitro* biological activity of at least 2 fold relative to that of rHuEPO on a molar basis.” Thus, the instant invention and the ‘292 patent are not identical in scope. Accordingly, Applicants believe that there is no statutory double patenting issue after the amendments are made in this Response to Office Action.

CONCLUSIONS

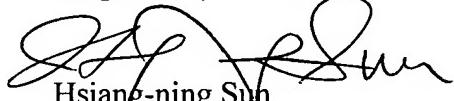
No new matter is introduced into the application by any and all of the amendments made herein to the claims, specification, and figures. All the amendments are supported by the originally filed application. Applicants respectfully request that the Commissioner enter these Amendments into the application as submitted herein.

Applicants respectfully submit that all of elected and non-withdrawn claims, **Claims 1-3, 7-12, 15, and 20**, are now allowable in their presently amended forms. An early and favorable action is respectfully solicited.

If the Examiner wishes to discuss the amendments or any other matter related to this application, Attorney for the Applicants may be reached at the phone numbers, and mailing address herein below.

The Commissioner is hereby authorized to charge any fees, *except issue fees*, or credit any overpayments related to this application to Deposit Account No. **50-2980**, maintained by the SUN Law Office PLLC.

Respectfully submitted,



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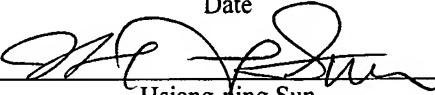
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CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as express mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450 Alexandria, VA 22313-1450 on

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Date



Hsiang-ning Sun

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